



ALLIANCE FOR RISK ASSESSMENT
ANNUAL REPORT
2012



A year of collaboration...

When it comes to public health protection, we all want the same thing. We all work hard to keep our workers safe, our environment unadulterated, and our children and families healthy. Working toward these common goals, we recognize that collaboration brings efficiency, synergy, and ultimately higher impact. Working together means shared data, higher quality science, and improved communication. And most importantly more lives saved.

The Alliance for Risk Assessment (ARA) is dedicated to bringing the human health risk assessment community together, inviting diverse interests, perspectives, and disciplines to the table. The world is changing- the science is advancing, new risks are presenting, and the opportunity in collaboration has never been greater.

Projects this past year have exemplified *ARA's* efforts to improve communication among groups, provide technical assistance to organizations in need, and promote science-based decision making. Our Annual Report gives an overview of key accomplishments of the year.

Purpose

The Alliance for Risk Assessment (*ARA*) is a collaboration of diverse organizations representing government, academic, industry, environmental and consulting perspectives, teaming up to protect public health. Working together, the *ARA* pools resources, information, and expertise to address chemical risk assessment issues that individual organizations cannot resolve on their own.

Guiding Principles of the Alliance for Risk Assessment

- Promote science-based decision making to protect human health
- Enhance harmonization and consistency in risk assessments through an open, transparent, multi-stakeholder approach
- Maintain access to groups of risk assessment experts that are normally not available within a single organization, agency or state
- Share costs, information, and human resources among multiple stakeholders to increase the capacity and quality of risk values

2012 Steering Committee

The *ARA* is guided by a Steering Committee comprised of individuals with governmental, tribal, academic, and non-government backgrounds. The Steering Committee reviews all *ARA* project proposals, determines whether the requested work is in alignment with the *ARA* mission and if the project should be accepted. The Steering Committee considers questions regarding conflicts of interest, and prioritizes project requests for the *ARA* Impact Fund. The Steering Committee includes:

- Anita Meyer, United States Army Corps of Engineers
- Annette Dietz, Oregon Department of Environmental Quality
- Bette Meek, University of Ottawa
- Edward Ohanian, United States Federal Employee
- Michael Dourson, Toxicology Excellence for Risk Assessment (TERA)
- Michael Honeycutt, Texas Commission on Environmental Quality (TCEQ)
- Ralph Perona, Neptune and Company, Inc.
- William Hayes, State of Indiana

Alliance for Risk Assessment Members



Toxicology Excellence for Risk Assessment
(TERA)
www.tera.org



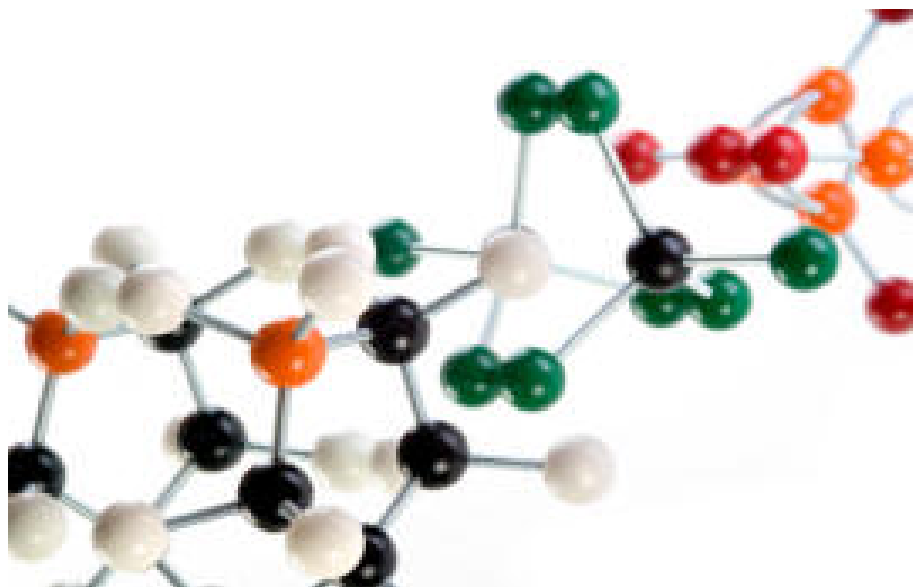
Noblis
www.noblis.org



Concurrent Technologies Corporation
www.ctc.com

The ARA currently obtains web hosting, office space, and administrative support from Toxicology Excellence for Risk Assessment (TERA), Concurrent Technology Corporation (CTC), and Noblis.

ARA Projects



Beyond Science and Decisions: From Problem Formulation to Dose-Response Assessment

To build on the vision set forth by the National Academy of Science's *Science and Decisions: Advancement of Risk Assessment* (2008), the Alliance for Risk Assessment has led a multi-party workshop series to:

- Bring diverse expertise and scientific opinion together to share information, ideas, and techniques
- Identify useful dose-response techniques for specified problem formulations, including characterization of assumptions, strengths and limitations, and how the techniques address key considerations in dose-response assessment
- Develop a Framework for selecting solution-oriented dose-response methods

Launched in 2010, the workshop series has held two workshops a year, with additional workshops planned for 2013. Led by an interdisciplinary Science Panel, the workshops highlight case study demonstrations of state-of-the-science risk methods as recommended by the NAS (2008). The series has received endorsement from over 55 risk organizations representing federal and state government, industry, environmental non-government organizations and academia. The sponsors and collaborators includes 12 government agencies, 19 industry groups, 7 scientific societies, 9 non-profit organizations/consortia, and 8 consulting groups:

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|---|--|--|--|
| <ul style="list-style-type: none"> ▪ Academy of Toxicological Sciences ▪ Agency for Toxic Substance & Disease Registry ▪ American Chemistry Council Center for Advancing Risk Assessment and Policy ▪ American Cleaning Institute ▪ American Petroleum Institute ▪ American Water Works Association ▪ Center for Food Safety and Applied Nutrition of the US Food Administration ▪ Consortium for Environmental Risk Management LLC (CERM) ▪ CropLife America ▪ Dose Response Specialty Group (Society for Risk Analysis) ▪ Electric Power Research Institute ▪ Environ | <ul style="list-style-type: none"> ▪ Ethylene Oxide Panel of the American Chemistry Council ▪ Georgia Department of Natural Resources ▪ Georgia Pacific ▪ Gradient ▪ Grocery Manufacturers Association ▪ The Hamner Institute of Health Sciences ▪ Hawai'i State Department of Health; Hazard Evaluation and Response ▪ Human Toxicology Project Consortium ▪ Illinois Environmental Protection Agency ▪ Indiana Department of Environmental Management ▪ Industrial Economics, Inc. ▪ International Copper Association Industrial Economics, Inc. | <ul style="list-style-type: none"> ▪ International Society of Regulatory Toxicology and Pharmacology ▪ The LifeLine Group ▪ Minnesota Pollution Control Agency ▪ The Naphthalene Council ▪ National Center for Toxicological Research ▪ New Zealand Ministry of Health ▪ Nickel Producers Environmental Research Association ▪ Nobilis ▪ NSF International ▪ Ohio Environmental Protection Agency ▪ Pastor, Behling & Wheeler, LLC ▪ Personal Care Products Council ▪ Regulatory and Safety Evaluation Specialty ▪ Risk Assessment Specialty Section (Society of Toxicology) | <ul style="list-style-type: none"> ▪ SC Johnson & Son ▪ Society of Chemical Manufacturers and Affiliates ▪ Society for Risk Analysis ▪ Society of Toxicology ▪ Summit Toxicology ▪ Styrene Information and Research Council ▪ Ted Simon Toxicology, LLC ▪ Texas Association of Business ▪ Texas Chemical Council ▪ Texas Commission on Environmental Quality ▪ Texas Industry Project ▪ Toxicology Excellence for Risk Assessment (TERA) ▪ U.S. Environmental Protection Agency |
|---|--|--|--|

Reports and presentations from all Workshops are available at: http://www.allianceforrisk.org/ARA_Dose-Response.htm.

The ARA Dose Response Framework is available at <http://allianceforrisk.org/Workshop/Framework/ProblemFormulation.html>.

Beyond Science & Decisions Project Collaborators



KIDS + CHEMICAL SAFETY

www.kidschemicalsafety.org

Our kids are surrounded by chemicals every day. As a parent, there are plenty of things to worry about. How do you know what is safe and what's not? Kids + Chemicals strives to be your best source of balanced, scientifically accurate chemical health information. We will alert you to the latest chemical-related health concerns, but also let you know when you can relax. Kids + Chemical Safety provides up-to-date health information on chemical hazards and chemical safe use in children.

Kids + Chemical Safety is administered by Toxicology Excellence for Risk Assessment (TERA), a non-profit and tax-exempt organization organized for scientific and educational purposes. TERA was founded on the belief that an independent non-profit organization can provide a unique function to protect human health by conducting scientific research and development on risk issues in a transparent and collaborative fashion and communicating the results widely.

Grants and in kind support used to develop and maintain kidschemicalsafety.com as well as develop new content have graciously been provided by:

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|--|--|
| + Alliance for Risk Assessment (ARA) | + Harvard Superfund Research Program |
| + American Chemistry Council (ACC) | + NSF International |
| + Cincinnati Children's Drug & Poison Control Center | + Individuals from the public |
| + Combined Federal Campaign (CFC) of the US Federal Govt | + Toxicology Excellence for Risk Assessment (TERA) |

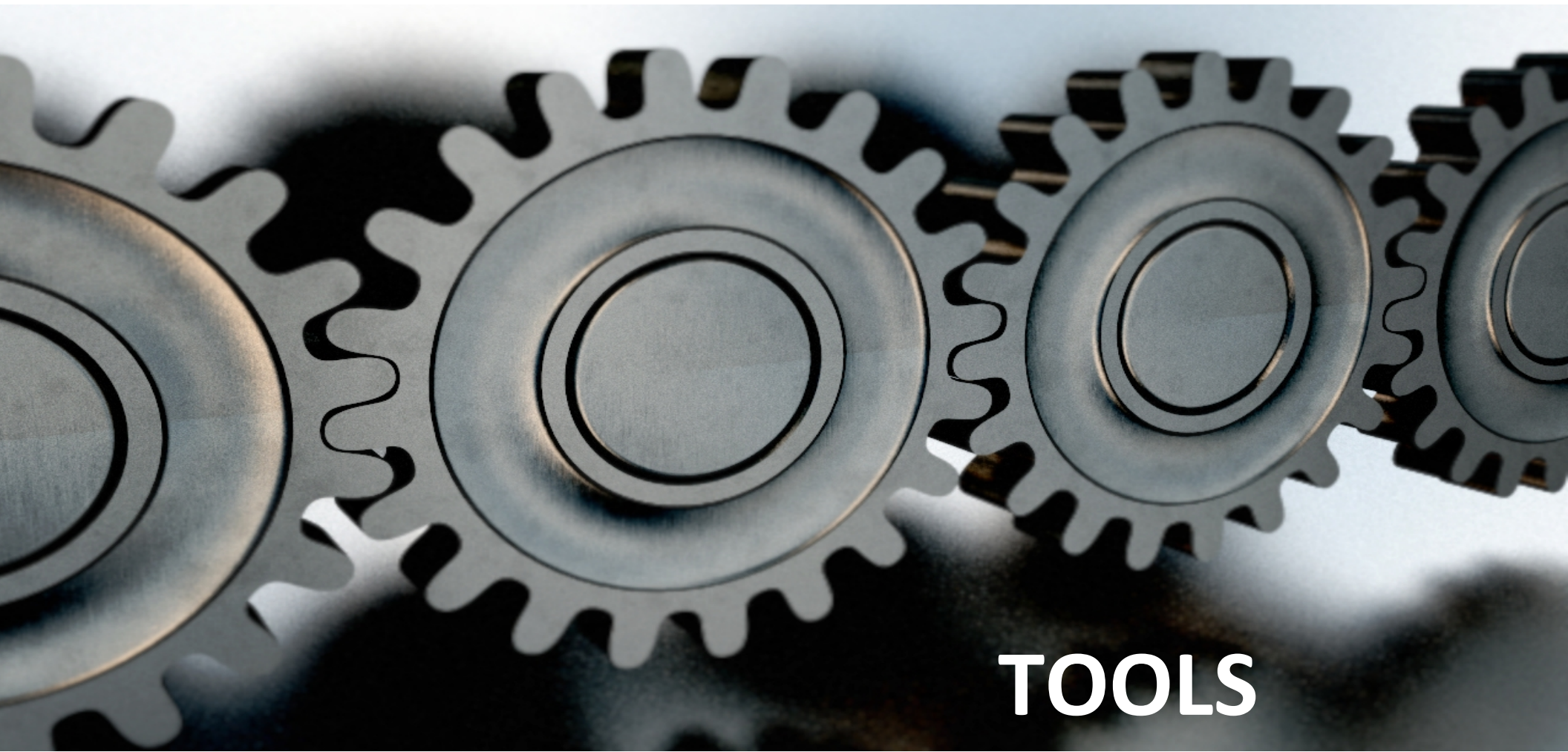


A coalition of interested parties is forming a workgroup to develop practical application guidance for the use of USEPA Trichloroethylene (TCE) Reference Concentration (RfC) and Inhalation Unit Risk (IUR) values for trichloroethylene for the purpose of site cleanup and closure. The goals of the coalition include:

1. Develop additional risk assessment guidance on how to interpret the non-cancer endpoint when it is used for deciding clean-up standards or acceptable exposure levels when closing sites.
2. Clarify the issues surrounding the potential developmental cardiac malformations for use in understanding clean-up standards and short term exposure levels.
3. Explore the margin of safety measures used to set the TCE RfC and evaluate if these measures are consistent with the baseline principles developed for determining the RfC.

Collaborators:





TOOLS

ITER

International
Toxicity Estimates
for Risk

RiskIE

Risk
Information
Exchange

**DOSE-
RESPONSE
FRAMEWORK**

SEARCH

State Environmental
Agency Risk
Collaboration for
Harmonization

International Toxicity Estimates for Risk (*ITER*)

The International Toxicity Estimates for Risk (*ITER*) database (www.tera.org/iter) provides chronic human health risk assessment data for over 750 chemicals from a variety of organizations worldwide. Data is provided in a side-by-side format, a synopsis explains differences in risk values derived by different organizations, and links to each organization's source document are included for more detailed information. *ITER* is also the only database that includes risk information from independent parties whose risk values have undergone independent peer review. The database includes values from the following organizations:

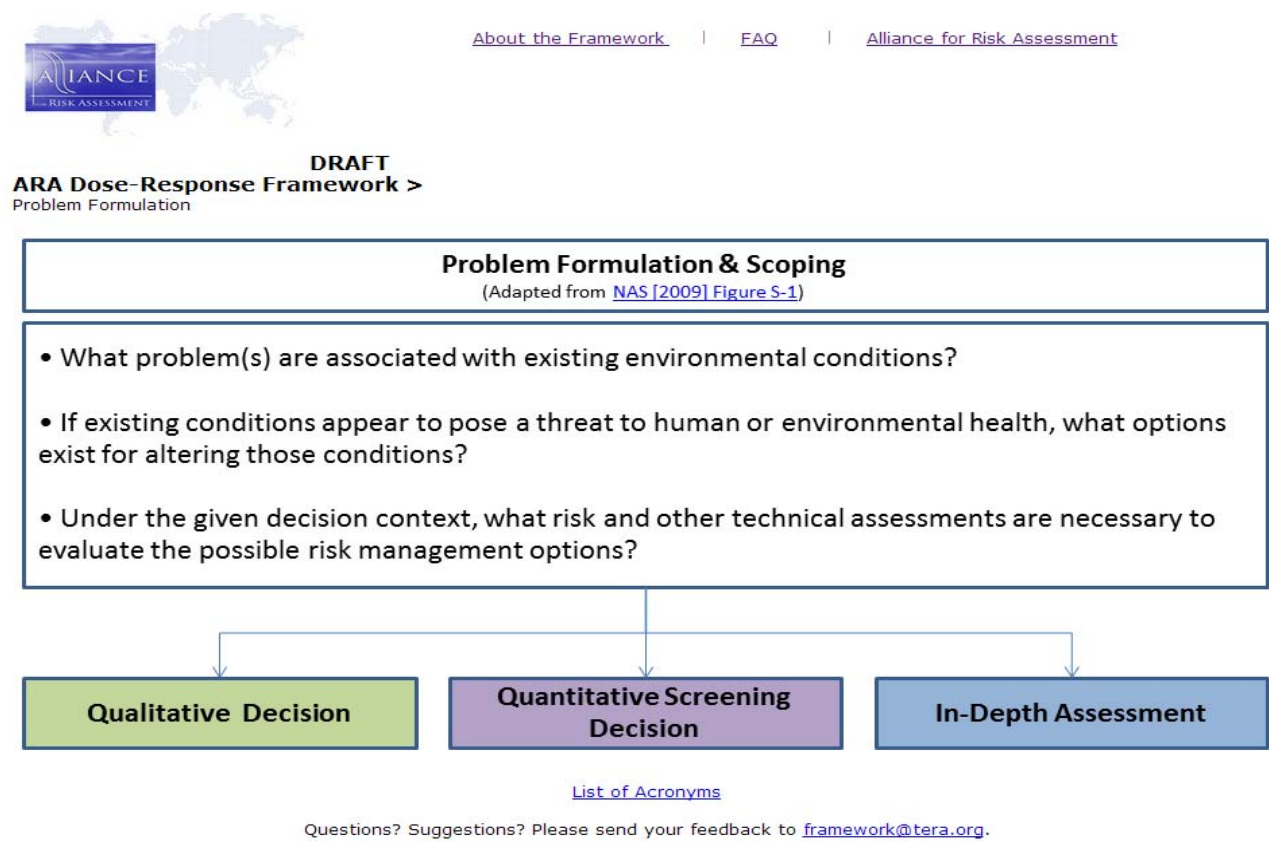
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Health Canada
- International Agency for Research on Cancer (IARC)
- International Programme on Chemical Safety (IPCS)
- NSF International
- National Institute of Public Health and the Environment (RIVM), The Netherlands
- Texas Commission on Environmental Quality
- U.S. Environmental Protection Agency (EPA)
- Independent parties whose risk values have undergone peer review

Risk Information Exchange (RiskIE)

The Risk Information Exchange (RiskIE) is a database of in progress chemical risk assessment work, and includes non-chemical information related to human health risk assessment, such as training modules, white papers and risk documents. RiskIE is available at <http://www.allianceforrisk.org/RiskIE.htm>. RiskIE currently tracks over 5600 in progress or recently completed risk assessment projects conducted by more than 35 different organizations representing 13 countries.

ARA Dose-Response Framework

The ARA Dose-Response Framework is a new interactive tool for selecting a dose-response technique based on the risk assessment's problem formulation, data availability, and regulatory context. With an abundance of dose response techniques available, and the rapid rate of new method development, the risk practitioner's selection of the appropriate method can be challenging. The Framework builds on the revised risk-assessment framework proposed by the National Academy of Sciences' *Science & Decisions: Advancing Risk Assessment* (2009), to provide a "roadmap" of current dose-response evaluation techniques. Methods are systematically organized into three categories; qualitative decision, quantitative screening decision, and in-depth assessment. The National Library of Medicine now includes the ARA Dose-Response Framework on the [Enviro-Health Links](#) page.



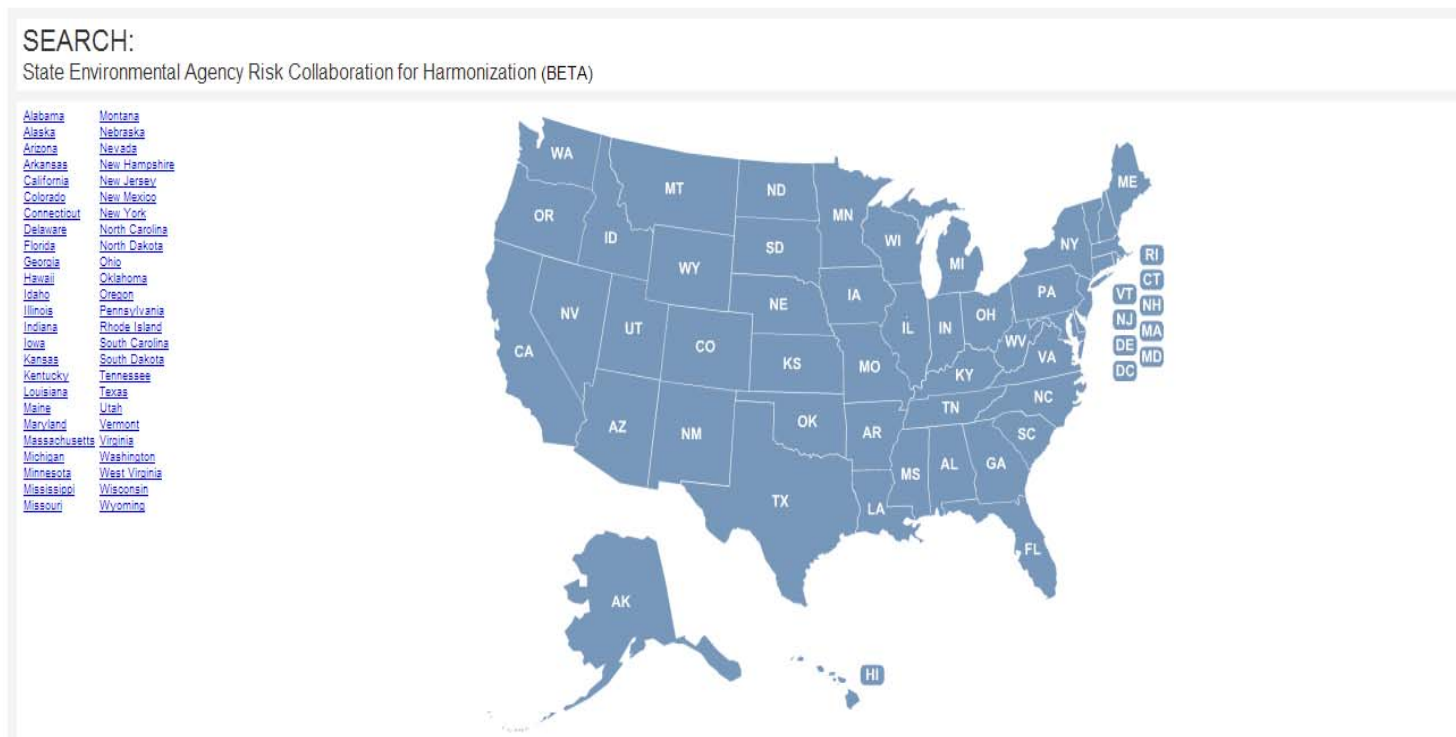
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 contact

<http://allianceforrisk.org/Workshop/Framework/About.html>

State Environmental Agency Risk Collaboration for Harmonization (SEARCH)

The Alliance is excited to introduce SEARCH (<http://www.allianceforrisk.org/search/index.html>), a free online interactive tool designed to help create a collaborative network among state agencies to provide a vehicle for efficiently sharing information and resources, and for the advancement of harmonization in risk values used among U.S. states. SEARCH, currently available in beta version, includes contact information for the department responsible for risk assessment with each state as an interactive map.

The SEARCH database was featured in the recently published *A Look at State-Level Risk Assessment in the United States: Making Decisions in the Absence of Federal Risk Values*. Effio, D. G., Kroner, O., Maier, A., Hayes, W., Willis, A. and Strawson, J. (2013) *Risk Analysis*, 33: 54–67



<http://www.allianceforrisk.org/search/index.html>

Finances

Event	Income	Expenses	Balance
Starting Balance			\$1,610
Project Fees	\$22,965		
Estimated In-kind Support	\$34,000(a)		
TERA Contribution	\$10,000		
ARA Management & Direct Expenses		\$22,270	
StateHELP Projects		\$929	
RiskIE		\$4,772	
SEARCH			
Ending Balance			\$6,604

(a) Value not counted in the balance.

ARA income is received from a 7% fee on projects conducted within the ARA framework and from donated time from various organizations. This income is used to cover the operational costs of the ARA, and to supplement the ARA Impact Fund. The Impact Fund is administered by the ARA Steering Committee to address pressing risk issues from States, Provinces or Tribes that are without financial support. In 2013, the Impact Fund begins with \$6,604.

ARA in the Press

Becker, R. "Beyond Science & Decisions" -- From Problem Formulation to Dose-Response Assessment. Society of Toxicology, Risk Assessment Specialty Section. Vol. 2(1). Summer 2011.

http://www.toxicology.org/ISOT/SS/RiskAssess/RASS_Newsletter_Volume2_Issue1_081811.pdf

Effio, D. G., Kroner, O., Maier, A., Hayes, W., Willis, A. and Strawson, J. A Look at State-Level Risk Assessment in the United States: Making Decisions in the Absence of Federal Risk Values. (2013) Risk Analysis, 33: 54–67

Hegstad M. Two Years On, Assessors Urge NAS to Clarify Advice on Linear Risk Method. Guest Perspective. Risk Policy Report 17(43). October 26, 2010. http://www.allianceforrisk.org/Workshop/RPR_ARA_Two_Years_On_Risk%2011-10.pdf

Hegstad M. EPA Framework Emphasizes Risk Management Options In Assessments Risk Policy Report 18(22). May 31, 2011. <http://allianceforrisk.org/Workshop/TERA%20%20EPA%20Framework%20%20RISK%20%2006-11.pdf>.

Hegstad M. Alliance Plans Panel to Address Key Scientific Issues In Risk Assessment. Risk Policy Report 18, (29). July 19, 2011 http://allianceforrisk.org/Workshop/RPR_Alliance_Plans_Panel_Risk_08-11.pdf.

Risk Group's Guidance to Address Uncertainty Issues in TCE Exposures. Risk Policy Report. January, 2013

Yohanan, S. ARA Seeks to Speed Risk Values For PFC Chemicals Due to Cleanup Fears. Risk Policy Report. October 16, 012, Vol 19. No. 41

Presentations & Posters

Tox Forum 2012

Meek, M.E. Problem Formulation to Dose-Response: Advances via the ARA Beyond Science and Decisions Workshops

Society of Toxicology 2012

Borgert C., Sargent E., Casella G., Dietrich D., McCarty, L, Golden, R., The Human Relevant Potency Threshold: Reducing Uncertainty by Human Calibration of Cumulative Risk Assessments.***SOT RASS Top 10 published paper for Demonstrating an Application of Risk Assessment***

Gentry, R., Van Landingham, C., Aylward, L., Hays, S. Use of Biomarkers in the Benchmark Dose Method

Haber, L. Beyond Science and Decisions: From Problem Formulation to Dose-Response - Framework

Kroner, O. Haber, L. Where the Rubber Meets the Road: A Practical Methods Compendium for Risk Assessors

Pottenger L.H; J. A. Swenberg; J. S. Bus, Endogenous DNA Damage: Considerations for Dose-Response and Risk Assessment **SOT RASS Top 10 abstracts***

Price, P., Juberg, D., Bartels, M., PBPK/PD Modeling of Key Events in a Toxicity Pathway - Implications for Determining Population Thresholds ***SOT RASS Top 10 abstracts***

Thompson, R., Haws, L., Harris M., Gatto, N., Proctor, D. Application of the U.S. EPA Mode of Action Framework for Purposes of Guiding Future Research: A Case Study Involving the Oral Carcinogenicity of Hexavalent Chromium. ***SOT RASS Top 10 published paper for Advancing the Science of Risk Assessment***

Society for Risk Analysis - New England Chapter

Dourson, M. Problem Formulation to Dose-Response: Advances via the Alliance for Risk Assessment Beyond Science and Decisions Workshops

Presentation at Society for Risk Analysis 2012

Meek M.E. Evolution of the ARA Framework on Problem Formulation to Dose-Response



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